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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,743	07/13/2001	Brian Paul Chadwick	28110/36120C	6792

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,743	CHADWICK ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 19-26 and 28-29 are pending and are being acted upon in this Office Action.

2. The USSNs (reference number A11-A13) cited on PTO 1449 filed 12/10/01 have been considered but crossed out because they are not appropriate for IDS.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "the antibody of claim 19 which comprises a detectable label" has no antecedent basis in base claim 19. It is suggested that the claim be recite "A labeled antibody wherein the antibody of claim 19 comprises a detectable label", for example. As for claim 26, it is suggested that the claim be recite "The labeled antibody of claim 25 .....or paramagnetic moiety".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick *et al* (Genomics 50: 357-367, 1998, PTO 1449) in view of Harlow *et al* (in Antibodies a Laboratory Manual, 1988, Cold Spring harbor laboratory publication, Cold Spring Harbor, NY, pages 92-94, pages 116-117, pages 626-629) or Campbell *et al* (in Monoclonal Antibody Technology, 1984, Elsevier Science Publisher, New York, NY, page 1-32; PTO 892).

Chadwick *et al* teach a polypeptide such as CD39L4 that has the amino acid sequence of 428 amino acids identical to the claimed SEQ ID NO: 6 of instant application (See Figure 1 on page 359, in particular). Chadwick *et al* teach that the reference human CD39L4 is a homologue of the mouse CD39L4 and shares extensive amino acid homology with other nucleotide triphosphatases in vertebrates and invertebrates (See abstract, in particular).

The claimed invention in claim 19 differs from the teachings of the reference only that the isolated antibody or fragment thereof which specifically binds to CD39L polypeptide having the amino acid sequence of SEQ ID NO: 6.

The claimed invention in claim 20 differs from the teachings of the reference only that the isolated antibody or fragment thereof which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6 is a monoclonal antibody.

The claimed invention in claim 21 differs from the teachings of the reference only that the antigen binding fragment is an antigen binding fragment of a monoclonal antibody which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6.

The claimed invention in claim 22 differs from the teachings of the reference only that a hybridoma which produces the monoclonal antibody which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6.

The claimed invention in claim 23 differs from the teachings of the reference only the isolated antibody or fragment thereof which specifically binds to CD39L polypeptide having the amino acid sequence of SEQ ID NO: 6 is a polyclonal antibody.

The claimed invention in claim 24 differs from the teachings of the reference only that the antigen binding fragment is an antigen binding fragment of a polyclonal antibody which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6.

The claimed invention in claim 25 differs from the teachings of the reference only that the antibody or fragment thereof which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6 wherein the antibody comprises a detectable label.

The claimed invention in claim 26 differs from the teachings of the reference only that the antibody or fragment thereof which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6 wherein the antibody comprises a detectable label wherein the label is radioisotope, affinity label, enzymatic label, or fluorescent label.

Harlow *et al* teach a method of producing polyclonal and monoclonal antibody (See page 92-94, page 116-117 in particular) as well as antigen binding fragment of any antibody (See page 626-629, in particular). Harlow *et al* teach that the problems of using multivalent antibodies on mammalian cells often will lead to capping and internalization of the antigen which can be overcome by using fragments of antibodies (See page 626 in particular). Harlow *et al* teach a method of making monoclonal antibody such as hybridoma or cell line that produces antibody that binds specifically to any antigen (See page 145-149, in particular). Harlow *et al* also teach a method of labeling any antibody with various labels such as enzyme, fluorescent, radioisotope (See chapter 9, in particular) for various detection assays. The advantages of enzyme labeling are longer shelf life, and higher sensitivity (See page 322, in particular). Harlow *et al* teach that the advantages of monoclonal antibody are their binding specificity, their homogeneity and their ability to be produced in unlimited quantities by hybridoma (See page 141, last full paragraph, in particular).

Campbell *et al* teach that "it is customary now for any group working on a macromolecule to both clone the gene encoding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (See page 29, section Basic Research, in particular).

Therefore, it would be been obvious to one having ordinary skill in the art at the time the invention was made to produce monoclonal or polyclonal antibody and antigen binding fragment thereof as taught by Harlow *et al* or Campbell *et al* that binds specifically to the CD39L4 polypeptide having the amino acid sequence identical to SEQ ID NO: 6 as taught by Chadwick *et al* for detection assay as taught by Harlow *et al* or for further characterization as taught by Campbell *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to make monoclonal or polyclonal antibodies to the claimed polypeptide based on the fact that it is a conventional practice in the art to do so for

further study, characterization and identification of a polypeptide as taught by Campbell *et al.* One having ordinary skill in the art at the time the invention was made would have been motivated with a reasonable expectation of success to make monoclonal antibody because Harlow *et al* teach that the advantage of monoclonal antibody are their specificity of binding, their homogeneity and their ability to be produced in unlimited quantities (See page 141, last full paragraph, in particular). One having ordinary skill in the art would have been motivated to make antibody fragment because Harlow *et al* teach that antibody fragments such as Fab can overcome the problem of capping and internalization of the antigen on mammalian cell when using multivalent antibodies (See page 626 in particular). Harlow *et al* teach that the advantages of enzyme labeling are longer shelf life, and higher sensitivity (See page 322, in particular).

8. Claim 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chadwick *et al* (Genomics 50: 357-367, 1998, PTO 1449) in view of Harlow *et al* (in Antibodies a Laboratory Manual, 1988, Cold Spring harbor laboratory publication, Cold Spring Harbor, NY, pages 92-94, pages 116-117, pages 626-629) or Campbell *et al* (in Monoclonal Antibody Technology, 1984, Elsevier Science Publisher, New York, NY, page 1-32; PTO 892) as applied to claims 19-26 above and further in view of U.S. Pat No. 5,858,682 (filed Aug 1996, PTO 892).

The combined teachings of Chadwick *et al,* Harlow *et al* and Campbell *et al* have been discussed supra.

The claimed invention in claim 28 differs from the combined teaching of the references only that a kit comprising the antibody or antigen binding fragment and a polypeptide having the amino acid sequence of SEQ ID NO: 6 or an immunologically reactive fragment of said polypeptide.

The claimed invention in claim 29 differs from the combined teaching of the references only that a kit comprising the antibody or antigen binding fragment which specifically binds to CD39L4 polypeptide having the amino acid sequence of SEQ ID NO: 6 and a wash reagent or a reagent capable of detecting the presence of a bound antibody.

The '682 patent teaches a kit comprising an antibody for diagnostic assays (See column 3, line 40; column 6, line 17; column 8, line 36, in particular). The '682 patent further teaches an antibody which is associated with a solid phase (see column 9, line 23, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody in the kit as taught by the '682 patent for the

antibody taught by Harlow or Campell et al that binds specifically to the CD39L4 along with the CD39L4 polypeptide as taught by Chadwick *et al* for diagnostic assays. One would have been motivated, with a reasonable expectation of success to do this for convenience and commercial expedience. A kit will allow for ease of use for the practitioner since all the necessary reagents, standard and instructions for use are included in a kit as taught by '682 (See column 8, line 36-57, in particular). From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidence by the references.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

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September 22, 2003

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